primary studies - published RCT

Inhaled versus systemic antibiotics and airway inflammation in children with cystic fibrosis and Pseudomonas.

Code: PM20146365 **Year:** 2010 **Date:** 2013 **Author:** Noah TL

Study design (if review, criteria of inclusion for studies)

Randomized, double-blind, placebo-controlled trial

Participants

Subjects with CF >8 years of age and FEV1 of 40-90% of predicted.

Interventions

Subjects were randomized to receive 646 mg glutathione in 4 ml (n = 73) or placebo (n=80) via an investigational eFlow(R) nebulizer every 12 hours for 6 months.

Outcome measures

FEV1 (absolute values), both as pre-post differences and as area under the curves (3, 6 months); pulmonary exacerbations; scores for quality of life; adverse event incidence.

Main results

FEV1 (absolute values), both as pre-post differences (P= 0.180) and as area under the curves (P= 0.205), were the primary efficacy endpoints and were not different between the glutathione group and the placebo group over the 6 months treatment period. Exploratory analysis showed an increase of FEV1 from baseline over placebo of 100 ml or 2.2 % predicted; this was significant at 3 months, but not later. Subjects receiving glutathione neither had less pulmonary exacerbations, nor better scores for quality of life. Whereas increased glutathione and metabolites in sputum demonstrated significant delivery to the lungs, there was no indication of diminished oxidative stress to proteins or lipids and no evidence for anti-inflammatory or anti-proteolytic actions of glutathione supplemented to the airways. The adverse event incidence was similar between glutathione and placebo.

Authors' conclusions

Inhaled glutathione in the dose administered did not demonstrate clinically relevant improvements in lung function, pulmonary exacerbation frequency and patient-reported outcomes. Glutathione delivery to the airways was not associated with changes in markers of oxidation, proteolysis or inflammation.

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See also

Pediatr Pulmonol. 2010 Mar;45(3):281-90.

Keywords

Adult; Aged; Antioxidants; Child; Glutathione; hydration; Inhalation OR nebulised; Isotonic Solutions; pharmacological_intervention; thiols; Respiratory System Agents;